K003070

NOV - 7 2000

SECTION 7

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

NEW DEVICE NAME: ETHIBOND EXCEL Valve Loop suture

PREDICATE DEVICE NAME: ETHIBOND EXCEL with PTFE (polytetrafluoroethylene) Pledgets

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510(k) SUMMARY

Device Description

ETHIBOND EXCEL Valve Loop suture is a product designation for a pledget (buttress) of a ePTFE (expanded polyetrafluoroethylene) that is prethreaded (attached) to ETHIBOND EXCEL polyester suture (reference NDA's / PMA's 17-804 and 17-809). Pledgets attached to sutures are used particularly as a buttress under sutures to prevent the sutures from tearing through friable tissue (e.g., heart tissue) as in valvular suturing in heart valve replacement procedures or other surgical procedures appropriate for the intended purpose of the device (i.e. protect the suture from tearing friable tissue).

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SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

Device Description (continued)

ETHIBOND EXCEL Valve Loop suture attached to ePTFE pledgets are sterile, braided, green and undyed (white) strands in size 2-0 with attached needle. The loop of the suture strand is formed by attaching the suture ends to a single needle. For the predicate device, each strand end of the ETHIBOND EXCEL suture prethreaded to PTFE pledgets is attached to a separate needle (two needles). A half-hitch knot is placed on the suture strand, where the strand exits the pledge.

The pledget is circular shaped with three (3) holes for threading the suture strand. Up to ten (10) ETHIBOND EXCEL Valve Loop sutures (equal numbers of dyed and undyed ETHIBOND EXCEL Valve Loop sutures, each prethreaded to ePTFE pledgets) may be contained within primary package.

Intended Use

ETHIBOND EXCEL suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures.

ETHIBOND EXCEL Valve Loop suture is used for soft tissue and cardiovascular procedures.

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SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

510(k) SUMMARY, Continued

Indications Statement	ETHIBOND EXCEL suture is indicated for use in general soft tissue approximation and /or ligation, including use in cardiovascular, ophthalmic, and neurological procedures. ETHIBOND EXCEL Valve Loop suture is used for soft tissue and cardiovascular procedures.
Technological Characteristics	Technologically the new device is the same as the predicate device in that consists of a nonabsorbable suture (ETHIBOND EXCEL suture) prethreaded to a pledget made from the generic material polytetrafluoroethylene (PTFE).
Performance Data	Bench-top evaluations were conducted to assess the performance characteristics of the new device when compared to the predicate device. Preclinical and clinical data was deemed unnecessary to demonstrate equivalence of the new device to the predicate device for its intended purpose.
Conclusions	Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Device under the Federal Food, Drug, and Cosmetic Act.
Contact	Gregory R. Jones Director, Regulatory Affairs ETHICON, Inc. Rt. #22, West Somerville, NJ 08876-0151
Date	September 29, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 7 2000

ETHICON, Inc.
c/o Mr. Gregory R. Jones
Director, Regulatory Affairs
P.O. Box 151
Somerville, NJ 08876-0151

Re: K003070
Trade Name: Ethibond Excel Valve Loop Suture
Regulatory Class: II (two)
Product Code: DXZ
Dated: September 29, 2000
Received: October 2, 2000

Dear Mr. Jones:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATION FOR USE

510(k) Number (if known): K003070

Device Name: ETHIBOND EXCEL Valve Loop Suture

Indications for Use: ETHIBOND EXCEL suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures.

ETHIBOND EXCEL Valve Loop suture is used for ~~soft tissue and~~ cardiovascular procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003070

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-9G)